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Par Pharmaceutical, Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BIOMARIN PHARMACEUTICAL INC.
and MERCK & CIE,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC.,
Defendant.

C.A. No. 3:15-cv-01706-MAS-TJB

**DEFENDANT PAR PHARMACEUTICAL, INC.'S
ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendant Par Pharmaceutical, Inc. ("Par"), by and through its attorneys, for its Answer to the Complaint of Plaintiffs BioMarin Pharmaceutical Inc. ("BioMarin") and Merck & Cie ("Merck") (collectively, "Plaintiffs"), hereby responds as follows:

NATURE OF THE ACTION¹

1. Paragraph 1 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the Complaint purports to be a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Par's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture and market a generic version of the pharmaceutical drug product Kuvan[®] prior to the expiration of U.S. Patent Nos. 7,566,462 ("the '462 patent"), 7,566,714 ("the '714 patent"), 7,612,073 ("the '073 patent"), 7,727,987 ("the '987 patent"), 8,003,126 ("the '126 patent"), 8,067,416 ("the '416 patent"), RE43,797 ("the '797 patent"), and 8,318,745 ("the '745 patent") (collectively, the "Patents-in-Suit").

THE PARTIES

2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of BioMarin. Par thus denies the allegations of Paragraph 2.

3. Par is without knowledge and information sufficient to form a belief as to the country of incorporation and principal place of business of Merck. Par thus denies the allegations of Paragraph 3.

4. Par admits it is a corporation incorporated under the laws of the State of Delaware. Par further admits having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Par denies the remaining allegations of Paragraph 4.

5. Par avers that it is a pharmaceutical company engaged in the manufacturing,

¹ Headings are reprinted here with the same language as used in Plaintiffs' Complaint simply for ease of reference, and do not constitute an admission by Par.

marketing, and selling, *inter alia*, of generic pharmaceutical products. Par denies any remaining allegations of Paragraph 5.

6. Par admits that it is registered to do business in the State of New Jersey under Business ID Number 0100071541, and is registered as a manufacturer and wholesaler of drugs in the State of New Jersey under Registration Number 5004032.

JURISDICTION AND VENUE

7. Paragraph 7 states a legal conclusion to which no response is required. To the extent a response is required, Par admits this Court has jurisdiction over the subject matter of this action only. Par denies any remaining allegations of Paragraph 7.

8. Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that it conducts business in this judicial district. Par admits specific personal jurisdiction in this judicial district for the limited purposes of this action only. Par denies any remaining allegations of Paragraph 8.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that it conducts business in this judicial district. Par avers that it is a pharmaceutical company engaged in the manufacturing, marketing, and selling, *inter alia*, of generic pharmaceutical products. Par admits that it maintains a place of business in this judicial district. Par admits specific personal jurisdiction in this judicial district for the limited purposes of this action only. Par denies any remaining allegations of Paragraph 9.

10. Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Par admits specific personal jurisdiction in this judicial district for the limited purposes of this action only. Par denies any remaining allegations of Paragraph 10.

11. Paragraph 11 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base venue on 28 U.S.C.

§§ 1391 and 1400(b). Par does not contest venue in this judicial district for the limited purpose of this action only. Par denies any remaining allegations of Paragraph 11.

THE PATENTS-IN-SUIT

12. Par admits that the '462 patent is titled "Stable Tablet Formulation." Par admits that the '462 patent, on its face, states its date of issue as July 28, 2009, with Steven Jungles, Mark A. Henderson, Victoria Sluzky, and Robert Baffi named as inventors. Par is without knowledge and information sufficient to form a belief as to whether the '462 patent was assigned to BioMarin. Par admits that what appears to be a copy of the '462 patent is attached to the Complaint as Exhibit A. Par denies that the United States Patent and Trademark Office duly and lawfully issued the '462 patent, and any remaining allegations of Paragraph 12.

13. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 13, and thus denies the same.

14. Par admits that the '714 patent is titled "Methods and Compositions for the Treatment of Metabolic Disorders." Par admits that the '714 patent, on its face, states its date of issue as July 28, 2009, with Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter named as inventors. Par is without knowledge and information sufficient to form a belief as to whether the '714 patent was assigned to BioMarin. Par admits that what appears to be a copy of the '714 patent is attached to the Complaint as Exhibit B. Par denies that the United States Patent and Trademark Office duly and lawfully issued the '714 patent, and any remaining allegations of Paragraph 14.

15. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 15, and thus denies the same.

16. Par admits that the '073 patent is titled "Methods of Administering

Tetrahydrobiopterin, Associated Compositions, and Methods of Measuring.” Par admits that the ’073 patent, on its face, states its date of issue as November 3, 2009. Par denies that the ’073 patent, on its face, states Daniel I. Oppenheimer, Alejandro Dorenbaum, and Augustus Okhamafe named as inventors. Par is without knowledge and information sufficient to form a belief as to whether the ’073 patent was assigned to BioMarin. Par admits that what appears to be a copy of the ’073 patent is attached to the Complaint as Exhibit C. Par denies that the United States Patent and Trademark Office duly and lawfully issued the ’073 patent, and any remaining allegations of Paragraph 16.

17. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 17, and thus denies the same.

18. Par admits that the ’987 patent is titled “Crystalline Forms of (6R)-L-Erythro-Tetrahydrobiopterin Dihydrochloride.” Par admits that the ’987 patent, on its face, states its date of issue as June 1, 2010, with Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter named as inventors. Par is without knowledge and information sufficient to form a belief as to whether the ’987 patent was assigned to Merck. Par admits that what appears to be a copy of the ’987 patent is attached to the Complaint as Exhibit D. Par denies the United States Patent and Trademark Office duly and lawfully issued the ’987 patent, and any remaining allegations of Paragraph 18.

19. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 19.

20. Par admits that the ’126 patent is titled “Stable Tablet Formulation.” Par admits that the ’126 patent, on its face, states its date of issue as August 23, 2011, with Steven Jungles, Mark Henderson, Victoria Sluzky, and Robert Baffi named as inventors. Par is without

knowledge and information sufficient to form a belief as to whether the '126 patent was assigned to BioMarin. Par admits that what appears to be a copy of the '126 patent is attached to the Complaint as Exhibit E. Par denies that the United States Patent and Trademark Office duly and lawfully issued the '126 patent, and any remaining allegations of Paragraph 20.

21. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 21, and thus denies the same.

22. Par admits that the '416 patent is titled "Methods and Compositions for the Treatment of Metabolic Disorders." Par admits that the '416 patent, on its face, states its date of issue as November 29, 2011, with Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter. Par is without knowledge and information sufficient to form a belief as to whether the '416 patent was assigned to BioMarin. Par admits that what appears to be a copy of the '416 patent is attached to the Complaint as Exhibit F. Par denies that the United States Patent and Trademark Office duly and lawfully issued the '416 patent, and any remaining allegations of Paragraph 22.

23. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 23, and thus denies the same.

24. Par admits that the '797 patent is titled "Methods of Administering Tetrahydrobiopterin." Par admits that the '797 patent, on its face, states its date of issue as November 6, 2012, with Daniel I. Oppenheimer, Alejandro Dorenbaum, and Augustus O. Okhamafe named as inventors. Par further admits that the '797 patent, upon information and belief, is a reissue of U.S. Patent No. 7,947,681. Par admits that what appears to be a copy of the '797 patent is attached to the Complaint as Exhibit G. Par denies that the United States Patent and Trademark Office duly and lawfully issued the '797 patent, and any remaining allegations of

Paragraph 24.

25. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 25, and thus denies the same.

26. Par admits that the '745 patent is titled "Crystalline Forms of (6R)-L-Erythro-Tetrahydrobiopterin Dihydrochloride." Par admits that the '745 patent, on its face, states its date of issue as November 27, 2012 with Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter named as inventors. Par is without knowledge and information sufficient to form a belief as to whether the '745 patent was assigned to Merck. Par admits that what appears to be a copy of the '745 patent is attached to the Complaint as Exhibit H. Par denies that the United States Patent and Trademark Office duly and lawfully issued the '745 patent, and any remaining allegations of Paragraph 26.

27. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 27, and thus denies the same.

THE KUVAN® DRUG PRODUCT

28. Admitted.

29. Paragraph 29 calls for a legal conclusion to which no response is required. To the extent a response is required, Par avers that, *inter alia*, the Patents-in-Suit are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with reference to NDA No. 022181. Par is without knowledge and information sufficient to admit or deny any remaining allegations of Paragraph 29, and thus denies the same.

ACTS GIVING RISE TO THIS ACTION

30. Par avers that it submitted ANDA No. 207200 ("Par's ANDA") pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking FDA approval to commercially manufacture and/or sell oral tablets containing 100 mg of sapropterin

dihydrochloride (“Par’s ANDA Product”), prior to the expiration of the ’462, ’714, ’073, ’987, ’126, ’416, ’797, and ’745 patents. Par is without knowledge and information sufficient to admit or deny any remaining allegations of Paragraph 30, and thus denies the same.

31. Par avers that it sent Plaintiffs a letter dated January 22, 2015, with an attached memorandum (collectively, “Par’s Notification”), stating that Par included certifications in its FDA submission, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par’s ANDA Product (the “Paragraph IV certification”). Par avers that it is seeking FDA approval to commercially manufacture and/or sell oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the Patents-in-Suit. Par denies any remaining allegations of Paragraph 31.

32. Paragraph 32 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 32.

33. Paragraph 33 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 33.

34. Paragraph 34 calls for a legal conclusion to which no response is required. To the extent a response is required, Par avers that Plaintiffs filed this Complaint within 45 days of receiving Par’s Notification. Par denies any remaining allegations of Paragraph 34.

COUNT ONE: INFRINGEMENT OF THE ’462 PATENT

35. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 34 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 34.

36. Paragraph 36 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 36.

37. Paragraph 37 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 37.

38. Paragraph 38 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 38.

39. Paragraph 39 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 39.

40. Paragraph 40 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 40.

41. Paragraph 41 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 41.

42. Par denies the allegations of Paragraph 42.

43. Par denies the allegations of Paragraph 43.

COUNT TWO: INFRINGEMENT OF THE '714 PATENT

44. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 43 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 43.

45. Paragraph 45 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 45.

46. Paragraph 46 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 46.

47. Paragraph 47 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 47.

48. Paragraph 48 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 48.

49. Paragraph 49 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 49.

50. Par denies the allegations of Paragraph 50.

51. Par denies the allegations of Paragraph 51.

COUNT THREE: INFRINGEMENT OF THE '073 PATENT

52. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 51 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 51.

53. Paragraph 53 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 53.

54. Paragraph 54 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 54.

55. Paragraph 55 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 55.

56. Paragraph 56 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 56.

57. Paragraph 57 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 57.

58. Par denies the allegations of Paragraph 58.

59. Par denies the allegations of Paragraph 59.

COUNT FOUR: INFRINGEMENT OF THE '987 PATENT

60. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 59 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 59.

61. Paragraph 61 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 61.

62. Paragraph 62 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 62.

63. Paragraph 63 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 63.

64. Paragraph 64 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 64.

65. Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 65.

66. Paragraph 66 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 66.

67. Par denies the allegations of Paragraph 67.

68. Par denies the allegations of Paragraph 68.

COUNT FIVE: INFRINGEMENT OF THE '126 PATENT

69. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 68 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 68.

70. Paragraph 70 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 70.

71. Paragraph 71 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 71.

72. Paragraph 72 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 72.

73. Paragraph 73 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 73.

74. Paragraph 74 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 74.

75. Paragraph 75 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 75.

76. Par denies the allegations of Paragraph 76.

77. Par denies the allegations of Paragraph 77.

COUNT SIX: INFRINGEMENT OF THE '416 PATENT

78. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 77 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 77.

79. Paragraph 79 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 79.

80. Paragraph 80 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 80.

81. Paragraph 81 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 81.

82. Paragraph 82 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 82.

83. Paragraph 83 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 83.

84. Par denies the allegations of Paragraph 84.

85. Par denies the allegations of Paragraph 85.

COUNT SEVEN: INFRINGEMENT OF THE '797 PATENT

86. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 85 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 85.

87. Paragraph 87 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 87.

88. Paragraph 88 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 88.

89. Paragraph 89 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 89.

90. Paragraph 90 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 90.

91. Paragraph 91 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 91.

92. Par denies the allegations of Paragraph 92.

93. Par denies the allegations of Paragraph 93.

COUNT EIGHT: INFRINGEMENT OF THE '745 PATENT

94. No response is required to the general reallegation and incorporation by reference of Paragraphs 1 through 93 of the Complaint. To the extent a response is required, Par incorporates by reference its responses to Paragraphs 1 through 93.

95. Paragraph 95 calls for a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 95.

96. Paragraph 96 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 96.

97. Paragraph 97 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 97.

98. Paragraph 98 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 98.

99. Paragraph 99 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 99.

100. Paragraph 100 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 100.

101. Par denies the allegations of Paragraph 101.

102. Par denies the allegations of Paragraph 102.

PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to the relief they seek in Paragraphs A–G or any relief at all for the allegations made in the Complaint.

SEPARATE DEFENSES

Par pleads the following defenses in response to Plaintiffs' allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein.

FIRST DEFENSE – FAILURE TO STATE A CLAIM

103. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE – INVALIDITY OF THE '462 PATENT

104. The claims of the '462 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

THIRD DEFENSE – NONINFRINGEMENT OF THE '462 PATENT

105. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '462 patent, either literally or under the doctrine of equivalents.

FOURTH DEFENSE – INVALIDITY OF THE '714 PATENT

106. The claims of the '714 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

FIFTH DEFENSE – NONINFRINGEMENT OF THE '714 PATENT

107. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '714 patent, either literally or under the doctrine of equivalents.

SIXTH DEFENSE – INVALIDITY OF THE '073 PATENT

108. The claims of the '073 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

SEVENTH DEFENSE – NONINFRINGEMENT OF THE '073 PATENT

109. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '073 patent, either literally or under the doctrine of equivalents.

EIGHTH DEFENSE – INVALIDITY OF THE '987 PATENT

110. The claims of the '987 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

NINTH DEFENSE – NONINFRINGEMENT OF THE '987 PATENT

111. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '987 patent, either literally or under the doctrine of equivalents.

TENTH DEFENSE – INVALIDITY OF THE '126 PATENT

112. The claims of the '126 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

ELEVENTH DEFENSE – NONINFRINGEMENT OF THE '126 PATENT

113. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '126 patent, either literally or under the doctrine of equivalents.

TWELFTH DEFENSE – INVALIDITY OF THE '416 PATENT

114. The claims of the '416 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

THIRTEENTH DEFENSE – NONINFRINGEMENT OF THE '416 PATENT

115. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '416 patent, either literally or under the doctrine of equivalents.

FOURTEENTH DEFENSE – INVALIDITY OF THE '797 PATENT

116. The claims of the '797 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

FIFTEENTH DEFENSE – NONINFRINGEMENT OF THE '797 PATENT

117. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '797 patent, either literally or under the doctrine of equivalents.

SIXTEENTH DEFENSE – INVALIDITY OF THE '745 PATENT

118. The claims of the '745 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

SEVENTEENTH DEFENSE – NONINFRINGEMENT OF THE '745 PATENT

119. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '745 patent, either literally or under the doctrine of equivalents.

NINETEENTH DEFENSE – NOT AN EXCEPTIONAL CASE

120. Par's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Par reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Par Pharmaceutical, Inc. ("Par") asserts the following Counterclaims against BioMarin Pharmaceutical Inc. ("BioMarin") and Merck & Cie ("Merck") (collectively, "Plaintiffs): (1) United States Patent No. 7,566,462 ("the '462 patent"); U.S. Patent No. 7,566,714 ("the '714 patent"); U.S. Patent No. 7,612,073 ("the '073 patent"); U.S. Patent No. 7,727,987 ("the '987 patent"); U.S. Patent No. 8,003,126 ("the '126 patent"); U.S. Patent No. 8,067,416 ("the '416 patent"); U.S. Patent No. RE 43,797 ("the '797 patent"); and U.S. Patent No. 8,318,745 ("the '745 patent") (collectively, "the Patents-in-Suit") are not infringed by the product described in ANDA No. 207200 and/or (2) are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

THE PARTIES

1. Par is a corporation organized and existing under the laws of Delaware with a place of business and corporate headquarters at One Ram Ridge Road, Chestnut Ridge, NY, 10977.

2. On information and belief, and based upon Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff BioMarin is a Delaware corporation, having its principal place of business at 770 Lindaro Street, San Rafael, California 94901.

3. On information and belief, and based upon Plaintiffs' allegations, Counterclaim-Defendant/Plaintiff Merck is a Swiss corporation having its principal place of business at WeissHausmatte, 6469 Altdorf, Switzerland.

NATURE OF THE ACTION

4. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declarations that the Patents-in-Suit are not infringed by the product described in Par's ANDA No. 207200 and/or are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties as demonstrated by, *inter alia*, Plaintiffs' filing of the Complaint, arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, as well as 21 U.S.C. § 355(c)(3)(D).

6. Plaintiffs have submitted to personal jurisdiction in this Court by suing Par in this judicial district, and previously, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. over the same patents (except for the '987 patent which was only asserted against Par), in this District. On information and belief, Plaintiffs sell products here, including the Kuvan® product at issue in this action, and Plaintiffs regularly conduct business in this District.

7. Venue is proper in this judicial district based on 28 U.S.C. §§ 1400(a) and/or 1391(b), (c), and (d).

BACKGROUND

8. The '462 patent, on its face, is titled "Stable Tablet Formulation," and states its date of issue as July 28, 2009.

9. The '714 patent, on its face, is titled "Methods and Compositions for the Treatment of Metabolic Disorders," and states its date of issue as July 28, 2009.

10. The '073 patent is titled, on its face, "Methods of Administering Tetrahydrobiopterin, Associated Compositions, and Methods of Measuring" and states its date of issue as November 3, 2009.

11. The '987 patent is titled, on its face, "Crystalline Forms of (6R)-L-Erythro-Tetrahydrobiopterin Dihydrochloride," and states its date of issue as June 1, 2010.

12. The '126 patent is titled, on its face, "Stable Tablet Formulation," and states its date of issue as August 23, 2011.

13. The '416 patent is titled, on its face, "Methods and Compositions for the Treatment of Metabolic Disorders," and states its date of issue as November 29, 2011.

14. The '797 patent is titled, on its face, "Methods of Administering Tetrahydrobiopterin," and states its date of issue as November 6, 2012.

15. The '745 patent is titled, on its face, "Crystalline Forms of (6R)-L-Erythro-Tetrahydrobiopterin Dihydrochloride," and states its date of issue as November 27, 2012.

16. On information and belief, and based on Plaintiffs' allegations, BioMarin is the owner of the '462, '714, '073, '126, '416, and '797 patents.

17. On information and belief, and based on Plaintiffs' allegations, Merck is the owner of the '987 and '745 patents.

18. On information and belief, BioMarin holds exclusive licenses to the '987 and

'745 patents.

19. On information and belief, and based upon Plaintiffs' allegations, the FDA approved NDA No. 022181 on December 13, 2007.

20. The '462, '714, '073, '987, '126, '416, '797, and '745 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for NDA No. 022181.

21. Par submitted ANDA No. 207200 to the FDA, requesting approval to engage in the commercial manufacture and/or sale in the United States of oral tablets containing 100 mg of sopropterin dihydrochloride, prior to the expiration of the '462, '714, '073, '987, '126, '416, '797, and '745 patents. Par made a certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") that no valid or enforceable claim of the '462, '714, '073, '987, '126, '416, '797, and '745 patents would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the product that is the subject of ANDA No. 207200 ("Par's ANDA Product").

22. On January 22, 2015, Par sent a letter to Plaintiffs stating that ANDA No. 207200 contained a Paragraph IV Certification regarding the Patents-in-Suit.

23. On March 6, 2015, Plaintiffs filed their complaint alleging infringement by Par of the Patents-in-Suit.

FIRST COUNT
(Declaration of Invalidity of the '462 Patent)

24. Par incorporates by reference Paragraphs 1 through 23 as if fully set forth herein.

25. The claims of the '462 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

26. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '462 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

27. Par is entitled to a judicial declaration that the '462 patent is invalid.

SECOND COUNT
(Declaration of Noninfringement of the '462 Patent)

28. Par incorporates by reference Paragraphs 1 through 27 as if fully set forth herein.

29. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '462 patent.

30. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '462 patent under the doctrine of equivalents.

31. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '462 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

32. Par is entitled to a judicial declaration that the '462 patent is not infringed.

THIRD COUNT
(Declaration of Invalidity of the '714 Patent)

33. Par incorporates by reference Paragraphs 1 through 32 as if fully set forth herein.

34. The claims of the '714 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101,

et seq.

35. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '714 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

36. Par is entitled to a judicial declaration that the '714 patent is invalid.

FOURTH COUNT
(Declaration of Noninfringement of the '714 Patent)

37. Par incorporates by reference Paragraphs 1 through 36 as if fully set forth herein.

38. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '714 patent.

39. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '714 patent under the doctrine of equivalents.

40. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '714 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

41. Par is entitled to a judicial declaration that the '714 patent is not infringed.

FIFTH COUNT
(Declaration of Invalidity of the '073 Patent)

42. Par incorporates by reference Paragraphs 1 through 41 as if fully set forth herein.

43. The claims of the '073 patent are invalid for failing to meet one or more

requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

44. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '073 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

45. Par is entitled to a judicial declaration that the '073 patent is invalid.

SIXTH COUNT
(Declaration of Noninfringement of the '073 Patent)

46. Par incorporates by reference Paragraphs 1 through 45 as if fully set forth herein.

47. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '073 patent.

48. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '073 patent under the doctrine of equivalents.

49. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '073 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

50. Par is entitled to a judicial declaration that the '073 patent is not infringed.

SEVENTH COUNT
(Declaration of Invalidity of the '987 Patent)

51. Par incorporates by reference Paragraphs 1 through 50 as if fully set forth herein.

52. The claims of the '987 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

53. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '987 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

54. Par is entitled to a judicial declaration that the '987 patent is invalid.

EIGHTH COUNT
(Declaration of Noninfringement of the '987 Patent)

55. Par incorporates by reference Paragraphs 1 through 54 as if fully set forth herein.

56. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '987 patent.

57. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '987 patent under the doctrine of equivalents.

58. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '987 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

59. Par is entitled to a judicial declaration that the '987 patent is not infringed.

NINTH COUNT
(Declaration of Invalidity of the '126 Patent)

60. Par incorporates by reference Paragraphs 1 through 59 as if fully set forth herein.

61. The claims of the '126 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

62. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '126 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

63. Par is entitled to a judicial declaration that the '126 patent is invalid.

TENTH COUNT
(Declaration of Noninfringement of the '126 Patent)

64. Par incorporates by reference Paragraphs 1 through 63 as if fully set forth herein.

65. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '126 patent.

66. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '126 patent under the doctrine of equivalents.

67. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '126 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

68. Par is entitled to a judicial declaration that the '126 patent is not infringed.

ELEVENTH COUNT
(Declaration of Invalidity of the '416 Patent)

69. Par incorporates by reference Paragraphs 1 through 68 as if fully set forth herein.

70. The claims of the '416 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

71. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '416 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

72. Par is entitled to a judicial declaration that the '416 patent is invalid.

TWELFTH COUNT
(Declaration of Noninfringement of the '416 Patent)

73. Par incorporates by reference Paragraphs 1 through 72 as if fully set forth herein.

74. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '416 patent.

75. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '416 patent under the doctrine of equivalents.

76. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '416 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory

judgment.

77. Par is entitled to a judicial declaration that the '416 patent is not infringed.

THIRTEENTH COUNT
(Declaration of Invalidity of the '745 Patent)

78. Par incorporates by reference Paragraphs 1 through 77 as if fully set forth herein.

79. The claims of the '745 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

80. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '745 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

81. Par is entitled to a judicial declaration that the '745 patent is invalid.

FOURTEENTH COUNT
(Declaration of Noninfringement of the '745 Patent)

82. Par incorporates by reference Paragraphs 1 through 81 as if fully set forth herein.

83. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '745 patent.

84. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '745 patent under the doctrine of equivalents.

85. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the

'745 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

86. Par is entitled to a judicial declaration that the '745 patent is not infringed.

FIFTEENTH COUNT
(Declaration of Invalidity of the '797 Patent)

87. Par incorporates by reference Paragraphs 1 through 86 as if fully set forth herein.

88. The claims of the '797 patent are invalid for failing to meet one or more requirements of patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

89. A definite and concrete, real and substantial, justiciable controversy exists between Par and Plaintiffs concerning the validity of the '797 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

90. Par is entitled to a judicial declaration that the '797 patent is invalid.

SIXTEENTH COUNT
(Declaration of Noninfringement of the '797 Patent)

91. Par incorporates by reference Paragraphs 1 through 90 as if fully set forth herein.

92. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the literal infringement of any valid or enforceable claim of the '797 patent.

93. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '797 patent under the doctrine of equivalents.

94. A definite and concrete, real and substantial, justiciable controversy exists

between Par and Plaintiffs concerning the alleged infringement by Par's ANDA Product of the '797 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

95. Par is entitled to a judicial declaration that the '797 patent is not infringed.

SEVENTEENTH COUNT
(Exceptional Case)

96. Par incorporates by reference Paragraphs 1 through 95 of its Counterclaims as if fully set forth herein.

97. This case is exceptional under 35 U.S.C. § 285 and Par is entitled to receive its reasonable costs and attorneys' fees incurred in connection with this action.

PRAYER FOR RELIEF

WHEREFORE, Par requests the following relief:

- a) Dismissing Plaintiffs' Complaint with prejudice and denying each request for relief made by Plaintiffs;
- b) Declaring all claims of the '462 patent invalid;
- c) Declaring all claims of the '462 patent not infringed, either literally or under the doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;
- d) Declaring all claims of the '714 patent invalid;
- e) Declaring all claims of the '714 patent not infringed, either literally or under the doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;
- f) Declaring all claims of the '073 patent invalid;
- g) Declaring all claims of the '073 patent not infringed, either literally or under the

doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;

h) Declaring all claims of the '987 patent invalid;

i) Declaring all claims of the '987 patent not infringed, either literally or under the doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;

j) Declaring all claims of the '126 patent invalid;

k) Declaring all claims of the '126 patent not infringed, either literally or under the doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;

l) Declaring all claims of the '416 patent invalid;

m) Declaring all claims of the '416 patent not infringed, either literally or under the doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;

n) Declaring all claims of the '745 patent invalid;

o) Declaring all claims of the '745 patent not infringed, either literally or under the doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;

p) Declaring all claims of the '797 patent invalid;

q) Declaring all claims of the '797 patent not infringed, either literally or under the doctrine of equivalents, by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's ANDA Product;

r) Declaring that Par has a lawful right to obtain FDA approval for the product as

described in ANDA No. 207200 and that Par has a lawful right to manufacture, import, use, sell, and/or offer to sell the product as described in ANDA No. 207200;

s) Shortening the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) to expire immediately;

t) Declaring that this case is exceptional under 35 U.S.C. § 285, and awarding Par its attorneys' fees, costs, and expenses in this action; and

u) Awarding Par such other and further relief as the Court deems just and proper.

March 31, 2015

Respectfully submitted,

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*Counsel for Defendant Counterclaim-Plaintiff
Par Pharmaceutical, Inc.*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Par hereby certifies that this matter is related to the *BioMarin Pharmaceutical Inc. et al v. Dr. Reddy's Laboratories, Inc. et al*, Civil Action No. 14-7203 (MAS)(TJB) matter pending before this Court, in that each of the patents asserted in that matter are also asserted in this matter. The undersigned counsel for Par further certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: March 31, 2015

s/ Sean R. Kelly
Sean R. Kelly

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Par hereby certifies that Par seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: March 31, 2015

s/ Sean R. Kelly
Sean R. Kelly